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EXAMINER

NOLAN, PATRICK J

ART UNIT

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29

Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 29

Application Number: 09/243,008
Filing Date: February 2, 1999
Appellant(s): Seed et al.

Karen L Elbing
For Appellant

MAILED
JUL 01 2003
GROUP 2900

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed April 9, 2003.

Real Party in Interest.

A statement identifying the real party in interest is contained in the brief.

Related Appeals and Interferences.

The brief does contain a statement identifying U.S.S.N. 08/488,184 is related to the parent application, 08//394,176 and is being appealed on different grounds

Status of Claims.

The statement of the status of the claims contained in the brief is correct.

Status of Amendments.

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The appellant's statement of the status of amendments contained in the brief is correct.

Statement of Invention.

The summary of invention contained in the brief is correct.

Issues.

The appellant's statement of the issues in the brief is correct.

Grouping of Claims.

Appellant's brief includes a statement that claims 44-47, 51, 52, 72-75, 79, 100 and 101 stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

Claims Appealed.

The copy of the appealed claims contained in the Appendix to the brief is correct.

References of record.

There are no references of record present to support the rejection of the instantly pending claims.

Grounds of rejections:

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 44-47, 51-52, 72-75, 79, 100 and newly added claim 101 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has no support in the originally filed claims or specification for the genus phrase language "an intracellular domain that does not signal to said cell to destroy a receptor-bound target cell or receptor-bound target infective agent", present in amended base claims 44 and 79.

Applicant's arguments filed 7-30-01 have been fully considered but are not found persuasive.

Applicant argues they have support for the claimed invention on page 48, lines 31-33, where they describe a chimera which has a full length extracellular domain, a full length transmembrane domain and a 3 amino acid intracellular domain. The specification further discloses this chimera was able to signal target cell destruction and they further characterize another chimera which had no intracellular domain and this chimera also was able to signal target cell destruction. From this disclosure Applicant's representative has concluded completely without any direct evidence that the first chimera that had only three amino acids intracellularly, was only working as a "nub" to anchor the chimera into the membrane and did not by her assertion act as a signal transmitter. It is because of these conclusory statements that Applicant's representative argues the specification has broad written support for a genus claim drawn to an "intracellular domain that does not signal to said cell to destroy a receptor-bound target cell or receptor-bound target infective agent". These amendments to the claims represent the creation of a sub-genus from the disclosure of a genus of receptor chimera

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and the possible disclosure of one chimera which includes a intracellular domain that may or may not signal said cell to destroy a receptor-bound target cell. This is not permitted as is recognized by the case law, "It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads." In re Smith 173 USPQ 679, 683 (CCPA 1972). See MPEP 2163.05(b).

Response to Appellant's arguments:

1. Claims 44-47, 51-52, 72-75, 79, 100 and newly added claim 101 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to the rejection Appellant has argued:

The presently pending claims are fully supported by the original specification at page 48 and by Figures 8A and 8B.

However as Appellant has readily acknowledged on page 10 last full paragraph of the Appeal Brief they have disclosed one species of cell comprising a chimeric receptor with an intracellular domain that does not signal said cell to destroy a receptor-bound target. How does this one species support the sub genus claim of all chimeric receptors with an extracellular domain, an intracellular domain that signals a cell to destroy a receptor bound target cell and wherein said cell further comprises any and all intracellular domains that does not signal said cell to destroy a receptor-bound target cell. The scope of such a claim is only limited by a practitioners imagination of various intracellular regions amino acid makeups, so long as said domain does not transmit a signal.

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Appellant has argued that the amendment of the claim to include a third region of the first receptor, the intracellular region that does not signal a cell to destroy the receptor bound target cell does nothing than highlight the fact that is the transmembrane domain that signals and that the intracellular domain does not, and that since the transmembrane domain is capable of signaling target destruction is supported by originally filed claim 44, and on this basis alone, the rejection should be reversed.

The Examiner does not dispute that Appellant has written support for a genus claim drawn to a cell comprising two chimeric receptors, wherein the first receptor has an extracellular domain capable of binding a target cell, and a transmembrane domain capable of signaling said cell to destroy a receptor bound target cell. In fact the Examiner had applied a 35 USC 103 rejection over the genus claim in Paper No 8., a rejection which was of record in the parent Application 08/394,176, said Application which is presently abandoned. In response to the rejection Appellant amended the claim by the insertion of the third part of the chimeric receptor, an intracellular domain, which Appellant clearly has support for in their originally filed specification, but said intracellular domain is required to not signal the destruction of the host. This property of such an intracellular domain is contrary to most tenets of T cell activation, since activation of T cells is accepted by those of skill in the art to occur via the intracellular domain. Said amendment also removed the prior art rejection. So in reviewing the specification it was clear Appellant had a lone example of a chimeric receptor that potentially had an intracellular domain that did not signal the receptor bound cell to destroy the target cell. In fact to support their claim the one example of an intracellular domain that did not transmit

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a signal to destroy the receptor bound target cell, appellant supplied a declaration in support of said fact, since the specification had no *ipsis verbis* support for such a recitation and the Appellant's argument of inherency could only be established by an evidentiary showing, by one of skill in the art. Lastly, Appellant's own specification discloses on page 50 lines, 5-10, that it was most likely by association with other chains that cytolytic activity of the activated cell was maintained. In other words Appellants first receptor was transmitting destruction of the target cell by associating with a full length chimera, that had a fully functioning intracellular domain.

Appellant argues no subgenus has been created.

In Appellant's original filed claims the first receptor had only two parts, an extracellular domain and a transmembrane domain, upon which art was applied. In response Appellant narrowed the claim by adding a third part to the first receptor, thereby creating a sub-genus claim of all first receptors with two parts to an amended claim with the original two parts but now the claim is required to have third part, an intracellular domain that does not signal said cell to destroy a receptor-bound target cell.

Appellant has argued that their specification has with reasonable clarity conveyed to a skilled artisan that the inventor was in possession of the invention at the time of filing.

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In appellant's specification it is clear they did work to determine how much of the intracellular domain could be cleaved and maintain cytolytic activity. What they determined was they could not cleave the entire domain, but could cleave large parts of it. At no point did they disclose that the chimeric receptors were not signaling destruction of the target cell via the intracellular domain, only that the transmembrane domain was capable. The amendment of the claimed invention to include an intracellular domain that does not signal a cell to destroy a target cell was only established in one working example via a declaration after the original filing for one species. Whether it would have been obvious to one of skill in the art that by creating a chimeric receptor that transmits a signal to destroy a target cell via the transmembrane domain would allow one to conclude that the same chimeric receptor is not at the same time doing so via its intracellular domain is not the legal standard for written description.

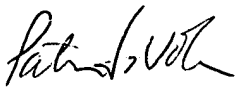
Further it is noted that obviousness is not the standard for the addition new limitations to the disclosure as filed. It is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1997).

For the above reasons, it is believed that the rejections should be sustained.

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June 27, 2003

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